PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James CASTILLO

Application No.: 09/954,494 Examiner: Kim, Vickie

Filed: September 17, 2001 Group Art Unit: 1614

For: ALCOHOL BASED TOPICAL ANESTHETIC FORMULATION AND METHOD

Attorney Docket: 3863.015

DECLARATION UNDER 37 C.F.R. §1.132

Honorable Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, James Castillo, 15412 15th Street, Lutz, Florida 33549, declare and state the following:

In March of 1980, I graduated from the University of Florida with a Bachelors Degree in Pharmacy.

I have been involved in research and development relating to pharmacology, and particularly anesthetics, since 1986, and consider myself an expert in this field.

I am familiar with the subject matter and prosecution history of the above-identified application, including the Office Action dated April 7, 2003.

My personal history has not changed since the Declaration Under 37 C.F.R. §1.132 and the Supplemental Declaration Under 37 C.F.R. §1.132 filed November 29, 2002, in the above-identified application.

I note the Examiner's position in the Office Action dated April 7, 2003, i.e., that Inagi et al. teach a local anesthetic for external use which is prepared by blending a homogeneous mixture of an anesthetic, oleic acid, an alcohol, and a pharmaceutical acceptable carrier. Furthermore, the Examiner indicated that the Inagi et al. reference teaches a process of making the composition comprising the steps of dissolving a mixture of a local anesthetic and oleic acid with alcohol, mixing the solution with other carriers to produce a homogeneous.

According to the Examiner, the limitations evaporation, remainder less than 1% or cool sensation as recited in Claims 1, 6, and 10 respectively are considered inherent features because it would have been occurring naturally when the solution is applied topically to the affected area.

I note that the Examiner based his indication on the teaching found at Table I and column 6, lines 10-25.

I have conducted the following comparative experimentation to demonstrate that, the limitations evaporation, remainder less than 1% or cool sensation as recited in Claims 1, 6, and 10 respectively cannot be considered inherent features of the composition disclosed by Inagi et al.

That is, in order to demonstrate the unexpected improvement in evaporation, the following experimentation was conducted by me, or under my direct supervision.

In this experimentation, the specific example cited by the Examiner was selected, namely Example 1 show in Table I and column 6, lines 10-25.

PROCEDURE

BETACAINE GEL (Present invention)

Ingredient	Amount
Carbopol 940 SPECTRUM	1.05 gm
Water, distilled	29.42 gm
Polysorbate 80	1.05 gm
Lidocaine	5.0 gm
Petrolatum, white	12.45 gm
Alcohol, Isopropyl	51.03 gm

DISSOLVE CARBOPOL IN HOT WATER(45 C-50 C). MIX WELL TO DISPERSE ALL THE CARBOPOL.

THERE SHOULD BE NO VISIBLE LUMPS OF CARPOBOL. ADD PS 80 IN SMALL AMOUNTS WHILE MIXING VIGOROUSLY.

HEAT PETROLATUM TO 45 C. DISSOLVE LIDOCAINE IN PETROLATUM. ADD THIS MIXTURE TO THE CARBOPOL,

PS 80, AND WATER MIXTURE. MIX WELL. SLOWLY ADD THE ALCOHOL TO THIS MIXTURE WHILE VIGOROUSLY MIXING.

INAGI ET AL. FORMULA NUMBER 1

Ingredient	Amount (% weight)
Lidocaine	5.0
Ethanol	33
Sodium caprylate	2.4
Polyvinyl alcohol	10.0
Sodium Carboxymethyl	1.0
Purified Water	48.53
Hydrochloric acid	0.07

The weight ratio alcohol/water is 0.68

The composition was prepared following the instruction on column 6, lines 10-25.

Five grams of each formulation were placed on glassine paper and then spread out so that each sample had the same surface area. The results are as follows:

Evaporation Test Results

Time(min)	Betacaine Gel Weight(gm)					Inagi Formula Number 1 Weight(gm)				
	Test 1	Test 2	Test 3	Average	% loss	Test 1	Test 2	Test 3	Average	% loss
0	4.65	4.65	4.65	4.65	0.00	4.65	4.65	4.65	4.65	0.00
5	4.06	3.70	3.73	3.83	17.63	4.52	4.35	4.29	4.39	5.66
10	3.47	3.02	2.89	3.13	32.76	4.27	4.05	4.04	4.12	11.40
15	2.85	2.12	2.06	2.34	49.61	3.97	3.83	3.86	3.89	16.42
20	2.11	1.91	1.89	1.97	57.63	3.75	3.70	3.74	3.73	19.78
25	1.89	1.79	1.73	1.80	61.22	3.58	3.57	3.65	3.60	22.58
30	1.76	1.59	1.60	1.65	64.52	3.43	3.49	3.57	3.50	24.80

CONCLUSION

As can be seen from the results of the test, the formulation of the present invention shows a remarkable evaporation rate over the composition of the Inagi et al. reference. This remarkable evaporation rate allows the kinetic of the formulation to change so that as the proportion of the remaining alcohol is reduced, a more concentrated level of anesthetization. Thus, the delivery rate of the anesthetic is markedly enhanced.

In addition, because the onset of the anesthetic is reduced, the waiting time from the patient is also reduced; thus, the patient has a more tolerant attitude.

As a side benefit, the evaporation of the alcohol cools the skin causing the patient to feel a soothing cool, numbing feeling, which psychologically prepares the patient to the effect of the anesthetic.

In the Inagi et al. reference, the acceptable delivery rate of the medicament that needs to be delivered through the skin is lowered because the low evaporation rate of the composition, thus the anesthetic will take a longer time to act. Furthermore, because of the low evaporation rate, it is possible that alcohol can interact with the patient's skin and cause irritation. As can be seen, the Inagi et al reference does not overcome the problem of the prior art.

In addition, because the onset of the anesthetic is reduced, the waiting time from the patient is also reduced, thus the patient has a more tolerant attitude.

As a side benefit, the evaporation of the alcohol cools the skin causing the patient to feel a soothing cool, numbing feeling, which psychologically prepares the patient to the effect of the anesthetic.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application of any patent issuing thereon.

Date: July 7, 2003

James Castillo